



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 19 1999 :55 AUG 23 10:17

Patricia B. Lieberman, Ph.D.
Center for Science in the Public Interest
1875 Connecticut Ave. NW
Suite 300
Washington, D.C. 20009

Docket 99P-0485/CP

Dear Dr. Lieberman:

This is a tentative response to the citizen petition (99P-0485/CP) which you submitted to the Food and Drug Administration (FDA) on behalf of the Environmental Defense Fund, Food Animal Concerns Trust, Public Citizen's Health Research Group and The Union of Concerned Scientists on March 11, 1999. The citizen petition requests that FDA rescind already approved subtherapeutic uses of medically important antibiotics in livestock feed.

According to the administrative regulations at 21 CFR 10.30, FDA is required to respond to a citizen petition within 180 days. FDA is currently considering the issues raised in your citizen petition, the comments submitted on your citizen petition and the comments to the agency's discussion paper entitled "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (the framework) 64 FR 887, January 6, 1999. Because of the complex nature of the action requested, which requires careful and thorough scientific, legal, and policy consultation, analysis and coordination within the agency, FDA will require additional time to issue a final response to your citizen petition.

FDA will issue a final response to your citizen petition upon completion of our analysis of the comments received on your citizen petition, the framework document, numerous consultations and the resolution of the scientific, legal and policy issues.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

99P0485

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cc:

HFV-1

HFV-6

HFV-100

HFV-200

HFA-305 - 99P-0485/CP1

Lieber'/GAMitchell/ar/08-12-99

concur: JDawson/final:GMitchell/ar/08-18-99

S:Mitchell:Lieber'